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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,452	02/23/2004	Jeffrey J. Cernohous	55970US008	9990

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EXAMINER	
EPPERSON, JON D	

ART UNIT	PAPER NUMBER
1639	

NOTIFICATION DATE	DELIVERY MODE
12/13/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/784,452	CERNOHOUS ET AL.	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/23/04; 9/22/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants response filed October 10, 2007 is acknowledged

Status of the Claims

2. Claims 1-22 are pending

3. Applicant elected without traverse Group I (claims 1-20 and 22) and claim 22 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant's election of species is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election of species has also been treated as an election without traverse (MPEP § 818.03(a) and/ or 37 CFR 1.111(b)). Therefore, claims 1-20 and 22 are examined on the merits in this action.

Information Disclosure Statement

4. The information disclosure statement filed February 23, 2004, fails, in part, to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because two publications cited therein, lack page numbers, a necessary element for consideration (e.g., see marked version of IDS). While the other patent and other publications cited therein, and supplied, therewith, have been considered as to the merits, the above cited publications have not. Applicant is advised that the date of any re-submission of these citations contained in this information disclosure statement or the submission of the missing element – their publication dates – will be the date of submission for purposes of determining compliance with the requirements based on the time of

filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPE § 609 C(1).

5. The references listed on applicant's PTO-1449 form have been considered by the Examiner. A copy of the form is attached to this Office Action (e.g., 2/23/04; 9/22/06).

Specification

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 1-20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. **Claims 1, 10, 20 and 22** recite the limitation "the synthesis" in line 1. There is insufficient antecedent basis for this limitation in the claim. Therefore, claims 1, 10 and all dependent claims are rejected under 35 USC 112, second paragraph.

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Neukermans (WO 97/22825) (Date of Patent is ***June 26, 1997***).

For ***claim 20***, Neukermans (see entire document) discloses a method for the synthesis of an array of polymers (e.g., see abstract; see also pages 20 and 21 which results in the synthesis of an array of DNA via PCR). Neukermans further discloses **(a)** providing an array of sealed flexible polymeric pouches (e.g., see figures 3 and 4 wherein the pouches are elements 124a, 124b, and 124c and/or 122; see also figure 11 wherein the pouches are elements 128 connected in series; see also page 21, first full paragraph; see also page 11, last paragraph wherein polyethylene/polyimide is disclosed as the material for making the pouch; see also page 14, last paragraph, pouch 108 is preferably made from ... flexible ... polymeric sheets; see also page 22, last paragraph disclosing thickness in the range of 0.001 inch; see also page 13, last paragraph; see also page 26, paragraph wherein a single sheet is used). Neukermans further discloses that each pouch attached to a conveyance apparatus (e.g., see figure 3 elements 158a, 158b, 158c or, alternatively, elements 128a, 128b, and 128c; elements 146 used in conjunction with elements 124a, 124b, and 124c may also be considered separately or together as part of the conveyance apparatus; see also page 16, paragraphs 1 and 2 wherein the peristalitic pump/syringe may be considered part of the conveyance apparatus). Neukermans also

discloses that each pouch containing a same first reactant and a same second reactant (e.g., see figure 11; see also pages 21 and 22 wherein reagents for PCR are set forth for the two reaction chambers shown in figure 11, which would include the DNA, heat stable polymerase, primers, etc. any of which would qualify as first/second reagents). Neukermans also discloses that at least a first pouch and a second pouch contains a similar volume ratio of first reactant to second reactant (e.g., see figure 11 wherein the contents of one chamber is shuttled back and forth to another second reaction chamber which would contain the same volume ratio of first reactant to second reactant before during and after the transport; see also page 21, last paragraph, especially, lines 26-30). Neukermans also discloses **(b)** conveying the array of sealed flexible polymeric pouches through a reaction zone exposing the first pouch to a first set of reaction conditions and exposing the second pouch to a second set of reaction conditions where the first set of reaction conditions are different than the second set of reaction conditions and cause the first reactant in each pouch to react with the second reactant in each pouch to produce an array of polymers (e.g., see figure 11; processing chambers 198; see also page 21, last paragraph, especially lines 26-27, "Temperature cycling can be accomplished by heating or cooling the processing chambers 198 [i.e., reaction zones], or, preferably, by periodically shuttling the liquid back and forth between the processing chambers 198 while maintaining the processing chambers 198 respectively at the two PCR temperatures [i.e., the chambers are kept at two different temperatures, or reaction conditions, and the liquid is cycled back and forth between the two]").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neukermans (WO 97/22825) (Date of Patent is ***June 26, 1997***) in view of McPherson et al. (PCR. M. J. McPherson and S. G. Møller. BIOS Scientific Publishers, Oxford. 2000, pages 9-21 and 67-87.).

For ***claim 1***, Neukermans discloses a method for the synthesis of an array of polymers (e.g., see abstract; see also pages 20 and 21 which results in the synthesis of an array of DNA via PCR). Neukermans et al. further disclose **(a)** providing an array of sealed flexible polymeric pouches (e.g., see figures 3 and 4 wherein the pouches are elements 124a, 124b, and 124c and/or 122; see also figure 11 wherein the pouches are

elements 128 connected in series; see also page 21, first full paragraph; see also page 11, last paragraph wherein polyethylene/polyimide is disclosed as the material for making the pouch; see also page 14, last paragraph, pouch 108 is preferably made from ... flexible ... polymeric sheets; see also page 22, last paragraph disclosing thickness in the range of 0.001 inch; see also page 13, last paragraph; see also page 26, paragraph wherein a single sheet is used). Furthermore, Neukermans et al. disclose that each pouch attached to a conveyance apparatus (e.g., see figure 3 elements 158a, 158b, 158c or, alternatively, elements 128a, 128b, and 128c; elements 146 used in conjunction with elements 124a, 124b, and 124c may also be considered separately or together as part of the conveyance apparatus; see also page 16, paragraphs 1 and 2 wherein the peristalitic pump/syringe may be considered part of the conveyance apparatus). Neukermans also discloses that each pouch contains a first reactant and a same second reactant (e.g., see figure 11; see also pages 21 and 22 wherein reagents for PCR are set forth for the two reaction chambers shown in figure 11, which would include the DNA, heat stable polymerase, primers, etc. any of which would qualify as first/second reagents). Neukermans also discloses **(b)** conveying the array of sealed flexible polymeric pouches through a reaction zone to cause the first reactant in each pouch to react with the second reactant in each pouch to produce an array of polymers (e.g., see figure 11; processing chambers 198; see also page 21, last paragraph, especially lines 26-27, "Temperature cycling can be accomplished by heating or cooling the processing chambers 198 [i.e., reaction zones], or, preferably, by periodically shuttling the liquid back and forth between the processing chambers 198 while maintaining the processing chambers 198 respectively at the two

PCR temperatures").

For ***claim 2***, Neukermans discloses the method according to claim 1 wherein the providing step further comprises providing an array of pouches that are linearly joined (e.g., see figure 11; elements 196/198 are linearly joined; see also figure 5 and discussion related thereto).

For ***claim 3***, Neukermans discloses the method according to claim 1 wherein the providing step further comprises providing an array of pouches that are linearly and horizontally joined (e.g., see figure 3-5 and 11 showing both linear and horizontal arrangements).

For ***claim 4-6***, Neukermans discloses the method according to claim 1 conveying the array of sealed flexible polymeric pouches through a reaction zone to cause the first reactant in each pouch to react with the second reactant in each pouch to produce an array of 90 different polymers (e.g., see page 19, first full paragraph disclosing the conveyance of portable microfluidic systems that are subsequently aligned via the registration pins 106 to insure that the pouches pass into the appropriate reaction zones; see also page 26). Neukermans do not state that 90 different polymers are produced but the Examiner contends that this would be an inherent feature of the PCR process as an enormous number of copies of the DNA are produced during the course of the synthesis including from 1 to 1,048,576 copies by the 20^{th} cycle (e.g., see McPherson et al., page 12, Table 2.1), which would include 10, 30 and 90 along the way.

For ***claim 7***, Neukermans discloses the method according to claim 1 further comprising the step of labeling each pouch (e.g., see figures 3-5 wherein the pouches are

labeled with element numbers).

For ***claim 9***, Neukermans discloses the method according to claim 1 further comprising the step of analyzing the polymer in each sealed flexible polymeric pouch by a non-destructive technique (e.g., see figure 12; see also page 23, paragraph 1 wherein non-destructive fluorescence analysis is disclosed; see also page 23, paragraph 2 wherein TIR is disclosed; see also figure 15 wherein CE is disclosed).

For ***claim 10***, Neukermans further discloses, in addition to the limitations set forth above for claim 1, the use of a captive pouch. For instance, element 108 may be viewed as "large" pouch in figure while elements 124a, 124b, 124c, 122, etc may be viewed as the "captive" pouches. Furthermore, the duplication of the large pouches to process multiple samples in parallel would be immediately envisioned. See, for example, *In re Harza*, (274 F.2d 669, 124 USPQ 378 (CCPA 1960)) where the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.

For ***claim 11***, Neukermans discloses the method according to claim 10 wherein the step of providing comprises providing a captive pouch containing a portion of the same first reactant or a portion of the same second reactant (e.g., see figure 11 wherein the liquid is shuttled back and forth and, as a result, each pouch contains a "portion" of the reagents at any one given time; see also page 21, last paragraph).

For ***claim 12***, Neukermans discloses the method according to claim 10 wherein the step of providing comprises providing a captive pouch containing a third reactant that is different than the first or second reactant (e.g., see figure 3 showing pouches for three

different reactants; see also figure 5 showing pouches for 4 different reactants corresponding to elements 124a-d).

For ***claim 13***, Neukermans discloses the method according to claim 10 further comprising the step of rupturing the captive pouch and releasing material within the captive pouch into the each sealed flexible polymeric pouch (e.g., see figure 7 wherien the rupturing occurs by applying an electric voltage to the piezoelectric element thereby rupturing the seal between elements 114 and 116).

For ***claim 14***, Neukermans discloses the method according to claim 13 wherein the rupturing step precedes the exposing step (e.g., see figure 3 wherein the rupturing that occurs during the piezoelectric valve switch precedes a heat exposure to element 122 via element 152).

For ***claim 15***, Neukermans discloses the method according to claim 13 wherein the rupturing step follows the exposing step (e.g., see figure 11 wherein the processing chambers are exposed to heat, etc. and then ruptured via another piezoelectric valve; see also figure 10 and corresponding text wherein many different configurations are disclosed).

For ***claim 16***, Neukermans discloses the method according to claim 15 further comprising the step of exposing the ruptured pouches to a controlled environment to cause the material within the captive pouch to react with the polymer in each sealed polymeric pouch (e.g., see figure 11 wherein the pouches are exposed to a controlled environment such as conditions amenable to PCR; see also page 21, last two paragraphs).

For ***claim 17***, Neukermans discloses the method according to claim 10 wherein

the step of providing comprises providing a captive pouch attached to each sealed flexible polymeric pouch (e.g., see figure 3 wherein the pouch 108 contains a captive pouch such as 124, 128 or 122; see also figure 5 showing captive pouches 124a-d). Please note that merely "duplicating" the number of pouches (i.e., element 108), which contain various captive pouches, to process more than one sample in parallel is not inventive. See, for example, *In re Harza*, (274 F.2d 669, 124 USPQ 378 (CCPA 1960)) where the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.

For ***claim 18***, Neukermans discloses the method according to claim 10 wherein the step of providing comprises providing a captive pouch free floating within each sealed flexible polymeric pouch (e.g., see page 15, first full paragraph, especially lines 15-16, "Entire areas of the sheets 114 and 116 may be laminated, or laminations may be formed only partially to outline the patterns [i.e., freely floating with respect to the parts that are not laminated]"; see also page 17, last paragraph, "It is not necessary to laminate together the entire areas outside of the reservoirs ... Laminating the peripheries of these areas is sufficient").

For ***claim 19***, Neukermans discloses the method according to claim 10 wherein the step of providing comprises providing more than one captive pouch within each sealed flexible polymeric pouch (e.g., see figures 3 and 5 disclosing more than one captive pouch).

For ***claim 20***, Neukermans anticipates the claimed invention (see 35 U.S.C. § 102(b) rejection above, which is incorporated in its entirety herein by reference) and, as a

result, also renders this claim obvious. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) ("anticipation is the epitome of obviousness"); see also *In re Skoner*, 517 F.2d 947, 950, 186 USPQ 80, 83 (CCPA 1975); *In re Pearson*, 494 F.2d 1399, 1402, 181 USPQ 641, 644 (CCPA 1974).

For ***claim 22***, Neukermans discloses in addition to the limitations set forth in claim 1, the use of a first and second reactant polymer (e.g., the primers or the template DNA strand) and also the use of a mixing chamber (e.g., see figure 11 wherein the liquid is shuttled back and forth or "tapped" periodically with a piston (e.g., see figure 11; see also page 22, paragraphs 1 and 2).

The prior art teachings of Neukermans differs from the claimed invention as follows:

For ***claims 1 and 8***, Neukermans fails to teach different volume ratio of first/ second reactants. Neukermans is silent on this point only mentioning that PCR is performed via thermocycling in the array of pouches disclosed therein.

However, McPherson et al. teach the following limitations that are deficient in Neukermans:

For ***claims 1 and 8***, McPherson et al. (see chapters 2 and 4) teach the use of PCR and optimization protocols related thereto. Specifically, McPherson et al. teach the use of adding different amounts/volumes of template, primer, reaction additives and enzyme to optimize PCR reactions that don't produce any product or, alternatively, produce too many products indiscriminately (e.g., see chapter 2 for general PCR setup and background; see chapter 4 for optimization, especially section 2.3, 2.10, 3 and table 4.1

disclosing various optimization protocols wherein the amount of one or more reagent is varied; see also section 2.3 with regard to setting up multiple samples (i.e., a titration) in parallel to test various amounts of a reagent).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use different volumes/amounts of PCR reagents as taught by McPherson et al. in the PCR method/apparatus as taught by Neukermans because McPherson et al. explicitly states that PCR methods often require optimization. Furthermore, a person of ordinary skill in the art would have been motivated to use the optimization conditions set forth in McPherson et al. to obtain the desired quantity of DNA product in cases where the "standard" conditions were not sufficient. In addition, a person of skill in the art would have been motivated to test more than one sample in parallel to increase the speed by which a large number of optimization conditions could be tested in a given period of time. A person of skill in the art would reasonably have expected to be successful because PCR is a widely used, routine technique employing "text book" optimization protocols (e.g., see McPherson et al., Table 4.1).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jon D. Epperson/
Primary Examiner, AU 1639